

REMARKS

The final Office Action dated May 16, 2007 has been carefully reviewed and the foregoing amendments and following remarks are made in response thereto. Claims 1-15 were pending in the application and claims 1-11 were under examination when the final Office Action was issued. Claims 12-14 have been cancelled without prejudice or disclaimer for filing in one or more divisional applications. Claims 1, 2, 4, 9, 10, and 15 have been amended and new claims 16-18 have been added. Claims 1, 4, 9, and 10 have been either re-worded or amended to reflect a change in claim dependency. Claim 2 has been amended to include nucleotides 1525-1643 of SEQ ID NO: 113, which corresponds to the smallest fragment (119 base pairs) of the *E. grandis* cOMT promoter which exhibited functional promoter activity. Support for this amendment can be found at page 12, line 24 to page 13, line 5 of the instant specification and SEQ ID NO: 6, Example 2 and Figure 10 in provisional application 60/425,087, which is incorporated by reference into the instant application. Claim 15 has been amended to specify that the desired phenotype compared between the transgenic and non-transgenic plants (non-transformed) is a change in lignification. Support for this amendment can be found at page 2, lines 25-30 and page 6, lines 19-27. Support for new claims 16-18 can be found throughout the specification, for example original claims 2 and 9; page 2, lines 25-30; page 3, lines 8-22; page 4, lines 12-15; page 6, lines 19-27; and page 15, lines 6-9. Applicants submit that the analysis of lignification in transformed and non-transformed plants and the comparison of the results are tools that are well within the skill of an artisan. Applicants support this assertion with the attached 1999 publication by Tuskan *et al.* (Exhibit A) that discloses techniques for determining wood properties of two types of trees. The Tuskan reference illustrates two high-throughput analytical approaches for characterizing the cell-wall chemical composition, which includes calculation of lignin content, to correlate phenotypic changes with genetic manipulations. The reference emphasizes the need for accurate, efficient methods to analyze cell-wall composition or feedstock composition due to the importance of feedstock quality in all biomass-based industries. See Tuskan *et al.*, page 56. Applicants also attach excerpts from a chapter in the text book "Wood and Cellulosic Chemistry" (Exhibit B), which describes common techniques for assessing changes in wood phenotype by analyzing the composition of the plant cell walls. The reference notes that lignin is one of the major components of cell walls and that wood analysis involves the separation and identification of each of the wood components. Moreover, the

reference states that “The methods of wood analysis are more or less standardized” and refers the reader to several reviews for detailed descriptions of the methods. See page 276 of the excerpt of Chapter 8. These two references are representative of the literature available before or at the time the application was filed and clearly demonstrate that analysis of cell wall composition to include lignin content was a common method employed by one of ordinary skill in the art to assess changes in wood phenotype.

In addition, the utility of a construct as claimed in claim 17 is illustrated in the attached reference by Mette et al. (Exhibit C). This reference, which is cited in the instant specification (see page 15, line 9), demonstrates that a similar construct causes transcriptional silencing in plants. Specifically, Mette shows that transformation of *Arabidopsis* and Tobacco plants with a construct comprising an inverted repeat of the nopaline synthase promoter under the control of the Cauliflower Mosaic Virus 35S promoter results in transcriptional silencing of the nopaline synthase gene. See Mette, page 5195 and Figure 1.

Upon entry of this amendment, claims 1-11 and 15-18 will be pending in the application. In view of the following remarks, Applicants respectfully request reconsideration and allowance of the pending claims. To be complete, Applicants have reiterated arguments made in the most recent response.

I. Rejections under 35 U.S.C. §112, 1st paragraph

Claims 1-11 stand rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement. The Examiner maintains that the specification as filed fails to convey to one of ordinary skill in the art that the inventors were in possession of the claimed invention. While the Examiner agrees that the promoters used in constructs cOMT1700 and cOMT667 exhibit vascular tissue specific promoter activity, she believes that the identity of the promoter sequence used in cOMT667 is unclear. The Examiner further explains that it is unknown whether the promoter sequence used in cOMT667, which has promoter activity, is contained within SEQ ID NO: 113 in light of Applicants’ statements that SEQ ID NO: 12 was a portion of SEQ ID NO: 113 and that it was 98.9% identical to residues within SEQ ID NO: 113 (Office Action, pg. 3-4). From these arguments, the Examiner concludes that there is only a single example of a fragment of SEQ ID NO: 113 that has

promoter activity and thus, the specification fails to disclose a representative number of species of the claimed genus by their complete structure and other identifying characteristics.

Applicants respectfully disagree with the Examiner's reasoning to support her rejection of claims 1-11. The specification as filed indicates that SEQ ID NO: 12 is 98.9% identical to the promoter comprising sequence of SEQ ID NO: 113 (nucleotides 1019-1676) (page 7, line 17-19 of the specification). In the response to the restriction requirement dated September 1, 2006, Applicants stated that "The current invention is drawn to a cOMT promoter sequence. SEQ ID NOS. 12 and 60 also contain portions of the cOMT promoter." Applicants further stated that "SEQ ID NO: 12 is a portion of the longer SEQ ID NO: 113 (See positions 1019-1675) As the three sequences contain extensive identity, Applicants believe the search and examination of these sequences can be made without serious burden." (see page 2 of the response dated 9/1/2006). The statements made by Applicants in the response to the restriction requirement and the description of SEQ ID NO: 12 in the specification accurately portrayed the relationship of SEQ ID NO: 12 to SEQ ID NO: 113 and were not contradictory as the Examiner believes. Because SEQ ID NO: 12 is 98.9% identical to the promoter region of SEQ ID NO: 113 (see Figures 1 and 2), it would be considered to be a "portion" of this promoter region with extensive identity to SEQ ID NO: 113. It is clear from the specification that the promoter sequence contained in cOMT667 is SEQ ID NO: 12 (see page 8, lines 11-15, Figure 3 description). Therefore, the promoter sequence in cOMT667 (SEQ ID NO:12) is considered to be a portion of the promoter region of SEQ ID NO: 113, both of which show promoter activity (see Examples 2 and 3, Figure 3-5).

The instant specification discloses two examples of cOMT promoter sequences (used in constructs cOMT 1700 and cOMT 667), which when transfected into plant cells show vascular tissue specific promoter activity (see Examples 2 and 3, Figures 3-5). Both of these promoter sequences are contained within SEQ ID NO: 113 or have 98.9% identity with a portion of SEQ ID NO: 113, which is the sequence of the *Eucalyptus grandis* cOMT gene and promoter (Figure 2). The promoter sequence used in the cOMT 1700 is the 5' UTR of the *Eucalyptus grandis* cOMT gene (bp 1-1643), which encompasses the promoter region of SEQ ID NO: 113 identified by bold type in Figure 2. The promoter sequence used in the cOMT 667 is SEQ ID NO: 12, which is 98.9% identical to the promoter region in SEQ ID NO: 113. Both of these promoter sequences contain *cis* elements that are thought to be important for vascular specific promoter

activity (see page 7, lines 15-17 of specification). The *cis* elements or motifs are underlined in the sequence in Figure 1 (SEQ ID NO: 12). A comparison between these identified motifs in SEQ ID NO: 12 and the promoter region of SEQ ID NO: 113 bolded in Figure 2 shows that the base pairs corresponding to these *cis* elements are identical between the two sequences.

In the previous response, Applicants direct the Examiner's attention to the two working examples and the U.S. provisional application 60/425,087, filed November 8, 2002, to which the present application claims priority and incorporates by reference (see page 1, lines 12-13). Applicants respectfully remind the Examiner that "information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed"(see MPEP 2163.07 (b)). This provisional application discloses SEQ ID NOs 2-6, which contain portions of the *E. grandis* promoter region identified in Figure 2 of the present application. SEQ ID NO: 2 of the provisional application is 543 base pairs in length and 100% identical to bp 1110-1643 of SEQ ID NO: 113. SEQ ID NOs 3-6 all have 3' ends that correspond to base pair 1643 of SEQ ID NO: 113, but are progressively shorter at the 5' end (SEQ ID NOs 3-6 are 485, 306, 293, and 119 base pairs in length, respectively). All of these promoter sequences demonstrated vascular tissue specific promoter activity when transfected into plant cells (see Example 2 and Figure 10 in provisional application 60/425,087). Furthermore, all of these promoter fragments contain two or more of the *cis* elements or motifs disclosed in the present application for SEQ ID NOs: 12 and 113 (see Figures 2-6, and 9 in provisional application 60/425,087). These data show that fragments of the *E. grandis* promoter smaller than SEQ ID NO:12 also demonstrate vascular specific promoter activity and all of the functional promoter sequences contain at least two of the conserved *cis* elements. Applicants submit that the above-identified relevant portions of provisional application 60/425,087, the present application's priority document, further support Applicants' position that the present application contained an adequate written description at the time of filing.

Applicants submit that the written description requirement is satisfied when a patent specification describes the claimed invention in sufficient detail to convey to one skilled in the art that the inventor had possession of the claimed invention as of the application filing date (see MPEP 2163, Section I.) An applicant may show possession of the invention by disclosure of sufficiently detailed, relevant identifying characteristics, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or

disclosed correlation between function and structure, or some combination of such characteristics (MPEP 2163, Section II, A. 3a.). The guidelines in the MPEP go on to state that for biomolecules “examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length. Although structural formulas provide a convenient method of demonstrating possession of specific molecules, other identifying characteristics or combinations of characteristics may demonstrate the requisite possession.” Furthermore, the Federal Circuit has held that there is no per se rule that requires an invention involving a biological macromolecule to contain a recitation of known structure to meet the written description requirement. *See Falkner v. Inglis*, 448 F.3d 1357, 1366, 79 USPQ2d 1001, 1007 (Fed. Cir. 2006). Applicants note that the independent claims are limited to a specific sequence (SEQ ID NO: 113) comprising a promoter region or limited to a specific sequence (SEQ ID NOs: 12 and 60) or specific nucleotides within those sequences that are disclosed in the present application. The structure of these specific promoter sequences as well as the identity of several *cis* motifs that are common to the functional promoters are disclosed within the instant specification. Moreover, Applicants have demonstrated the function of several promoters with these structural elements (bp 1-1643 of SEQ ID NO: 113, SEQ ID NO: 12 in Examples 2 and 3 of the instant specification, and several fragments of the promoter region of SEQ ID NO: 113 in Example 2 of U.S. provisional application 60/425,087, which was incorporated by reference as of the filing date). Given this disclosure, one of ordinary skill in the art would be able to determine appropriate functional promoter sequences and transform plants with the methods disclosed in the application. In view of these comments, Applicants hereby submit that the claimed invention is adequately described and meets the requirements of 35 U.S.C. §112, first paragraph. Thus, Applicants respectfully request that the rejection of claims 1-11 be withdrawn.

CONCLUSION

This reply is fully responsive to the Office Action dated May 16, 2007. In view of the above amendments and remarks, it is believed that the present set of claims are now in condition for allowance. Applicants respectfully submit that the claims define patentable subject matter. If, in the opinion of the Examiner, a further telephonic conference would expedite any minor

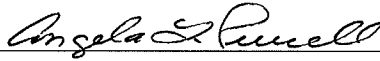
issues with regard to the pending claims, the Examiner is invited to call the undersigned practitioner.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-1283.

Respectfully submitted,

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LIST OF EXHIBITS

Exhibit A- Article entitled “Two High-Throughput Techniques for Determining Wood Properties as Part of a Molecular Genetics Analysis of Hybrid Poplar and Loblolly Pine”, *Applied Biochemistry and Biotechnology* (1999) Vol. 77-79: 55-65 by Tuskan *et al.*

Exhibit B- Excerpts from Chapter 8, “ Chemical Characterization of Wood and Its Components” by Baeza and Freer in Wood and Cellulosic Chemistry , eds. D.N.-S. Hon and N. Shiraishi (2001), Marcel Dekker, Inc. New York.

Exhibit C-Article entitled “Transcriptional silencing and promoter methylation triggered by double-stranded RNA”, *The EMBO Journal* (2000) Vol. 19: 5194-5201 by Mette *et al.*